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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 10/29/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/485,845

Applicant(s)
FUNAMIZU et al.

Examiner
Brenda Coleman

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1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 22, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-84 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Claims 61-84 are pending in the application.

This action is in response to applicant's amendment filed August 22, 2002. Claims 33-60 were canceled and claims 61-84 are newly added.

Response to Amendment

Applicant's arguments filed August 22, 2002 have been fully considered with the following effect:

1: With regards to the rejection as being drawn to an improper Markush group of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicant's stated that "Claim 33 (now claim 61) is amended to specify a A²N-" and "since the definition of A² is quite clear, the rejection is overcome".

In re Weber 198 USPQ 328 states that "[a] Markush-type claim is directed to "independent and distinct inventions," is two or more of its members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s)". Weber goes on to state in the next paragraph that "[i]f the claim is of that nature, the examiner is authorized to reject it as an improper Markush claim and for misjoinder under 35 U.S.C. 121 and to require the applicant to restrict the application to a single invention".

A reference anticipating one invention, would not render obvious the others, for example benzothiazepine amine is different from pyrrolylidine, isoindoline, quinoline, phenothiazine, etc.

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The elected invention which was examined in pending claims 61-84, is drawn to compounds, compositions and method of use of the compounds of formula I where A² as claimed herein is benzothiazepine, benzoxazepine or dibenzoxazepine.

Claims 61-84 are rejected as being drawn to an improper Markush grouping. For reasons of record and stated above.

2. With regards to the 35 USC § 112, enablement rejection of claims 33-36, 38-41 and 43-60 of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicant's argument are that the "amendment of claim 33 (now claim 61) significantly restricts the scope" and that "one skilled in the art could reasonably extrapolate the activities of representatives of the claimed compounds to the other compounds embraced by the claims which have not been tested".

The nature of the invention in the instant case, has claims which embrace a wide range of chemically and physically distinct compounds, wherein A² is a single or fused ring, each ring constituting A² is an aliphatic or aromatic ring which may have at least one hetero atom. The

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exact nature of this substituent is vague and indefinite in that it is not clear exactly how large the substituent may be. While several specific aliphatic or aromatic rings are disclosed for the variable A² by way of examples, there is insufficient guidance for preparing additional heterocyclic or heteroaromatic rings. Markush claims must be provided with support in the disclosure. Markush claims are subject to rejection based upon the lack of supporting disclosure when the “working examples” fail to include written description(s) which teach how to make and use Markush members embraced thereby in full, clear, and exact terms. See *In re Fouche* 169 USPQ 429. The compounds tested are not seen as adequately representative of the compounds encompassed by the extensive Markush groups instantly claimed for the uses instantly asserted and claimed.

Claims 61, 62, 64-66 and 68-84 are rejected under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For the reasons stated above and in the last office action.

3. The applicant's amendments are sufficient to overcome the 35 USC § 112, first paragraph rejection labeled 6a. However, with regards to the 35 USC § 112, enablement rejection of claims 33-60 labeled paragraph 6b of the last office action, the applicant's arguments have been fully considered but are not found persuasive.

- b) The applicants arguments are that “indolylalkyl and quinolylalkyl are mentioned as examples of B in claim 39 (now claim 64)” and that “ these groups are

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encompassed by the term “arylalkyl” in claim 33 (now claim 64)”. However, the term “aryl” used in the definition of B is unclear, since normally this would only refer to carbon containing groups such as phenyl, naphthyl etc, whereas in claim 64 the definition of B includes indolylalkyl and quinolylalkyl. It appears that this term is meant to encompass also heteroaromatic radicals such as indole and quinoline.

Note: In re Hill 73 USPQ 482 regarding distortion of art-recognized terms.

Claims 61-66 and 68-84 are rejected under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For the reasons stated above and in the last office action.

4. The applicant's amendments are sufficient to overcome the 35 USC § 112, second paragraph rejections labeled 7a), 7b), 7c), 7d), 7u), 7v), 7af) and 7aj) maintained in the last office action. However, with regards to the 35 U.S.C. § 112, second paragraph rejections labeled 7h), 7q), 7s), 7w) and 7aa) maintained in the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

h) The applicants' stated that “the definition of A³, A⁴ and Z in claim 36 (now claim 62) is amended to recite intended substituents”. However, the definition of Z in claim 62 has not been amended to recite intended substituents.

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Claim 62 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

- q) The applicants' stated that "claim 39 (now claim 64) corresponding to canceled claim 7, is amended to delete substituted". However, claim 82 still claims substituted alkyl, substituted cycloalkyl or aryl, arylalkyl or arylalkoxyalkyl which may be substituted on their aromatic ring.

Claim 82 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

- s) The applicants' stated that "both indolylalkyl and quinolylalkyl are encompassed by the term arylalkyl". However, the term "aryl" used in the definition of B is unclear, since normally this would only refer to carbon containing groups such as phenyl, naphthyl etc, whereas in claim 64 the definition of B includes indolylalkyl and quinolylalkyl. It appears that this term is meant to encompass also heteroaromatic radicals such as indole and quinoline. Note: In re Hill 73 USPQ 482 regarding distortion of art-recognized terms.

Claim 64 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

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- w) The applicants' stated that "the definition of R^5 , R^6 , R^7 , R^8 , R^1 and R^2 is amended to read --- R^5 , R^6 , R^7 and R^8 can be taken together with R^1 and R^2 and the bridging group which links R^5 , R^6 , R^7 or R^8 to R^1 or R^2 to form a carbocycle or heterocycle ---". However, R^1 and R^2 are bond to nitrogen atoms in the definition of D and thus any ring formed by the definition of R^5 , R^6 , R^7 , R^8 taken together with R^1 and R^2 will always yield a heterocyclic ring. Thus it is not known how R^5 , R^6 , R^7 , R^8 taken together with R^1 and R^2 can form a carbocyclic ring.

Claims 61-66 and 68-84 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

- aa) The applicants' stated that "the definition of R^5 , R^6 , R^7 and R^8 in claim 33 (now claim 61) is amended to read --- R^5 and R^7 , or R^6 and R^8 can be taken together with the carbon atoms to which R^5 and R^7 , or R^6 and R^8 are bonded to form a carbocycle or heterocycle ---". However, when R^5 and R^7 or R^6 and R^8 are taken together they form a carbocyclic ring not a heterocyclic ring.

Claims 61-66 and 67-84 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

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5. The applicant's amendments are sufficient to overcome the 35 USC § 112, first paragraph rejections of claims 33-41 and 43-60 labeled paragraph 12 of the last office action, which are hereby **withdrawn**.

6. The applicant's amendments are sufficient to overcome the 35 USC § 112, first paragraph rejection of claims 33-39 and 43-60 labeled paragraph 13 of the last office action, which is hereby **withdrawn**.

7. The applicant's amendments are sufficient to overcome the 35 USC § 112, first paragraph rejection of claims 36-41 and 43-60 labeled paragraph 14 of the last office action, which is hereby **withdrawn**.

8. The applicant's amendments are sufficient to overcome the 35 USC § 112, first paragraph rejection of claim 49 labeled paragraph 15 of the last office action, which is hereby **withdrawn**.

9. The applicant's amendments are sufficient to overcome the 35 USC § 112, first paragraph rejection of claims 36-41 and 43-60 labeled paragraph 16 of the last office action, which is hereby **withdrawn**.

10. The applicant's amendments are sufficient to overcome the 35 USC § 112, second paragraph rejections labeled 17a)-17d), 17l), 17m) and 17o-17y) of the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph

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rejections labeled 17e), 17f), 17g), 17h), 17i), 17j), 17k) and 17n) of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

- e) The applicants' stated that "the definition of R^5 and R^6 , or R^7 and R^8 are bonded, respectively, to form carbonyl, thiocarbonyl or imino" and that "the limitation $=NH$ in the definition of D in claim 41 is encompassed by imino in claim 34". However, claim 66 is dependent upon claim 65 not claim 61 where the definition of D is of a narrower scope than the definition of D in claim 61.

Claim 66 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

- f) The applicants' stated that "claim 33 (now claim 61) states R^2 and R^3 are independently hydrogen, alkyl, arylalkyl which may be substituted on its aromatic ring, or arylalkoxyalkyl which may be substituted on its aromatic ring, acyl, amidino, alkoxycarbonyl" and that "the limitation $C(=NH)NH_2$ is encompassed by amidino". However, claim 66 is dependent upon claim 65 not claim 61 where the definition of R^2 and R^3 is of a narrower scope than the definition of R^2 and R^3 in claim 61.

Claim 66 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

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- g-j) The applicants' stated that "claim 33 (now claim 61) states R^5 , R^6 , R^7 and R^8 can be taken together with R^1 or R^2 and the bridging group which links R^5 , R^6 , R^7 or R^8 to R^1 or R^2 to form a carbocycle or heterocycle" and that "the limitations 2-aminopyrrol-1-yl, 4-aminopiperid-1-yl, 3-amino-4-hydroxypyrrol-1-yl and 3-amino-5-ethoxycarbonylpyrrol-1-yl are encompassed by heterocycle in claim 33". However, claim 66 is dependent upon claim 65 not claim 61 where the definition of R^5 , R^6 , R^7 and R^8 is of a narrower scope than the definition of R^5 , R^6 , R^7 and R^8 in claim 61.

Claim 66 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

- k) The applicants' stated that "claim 41 (now claim 66) is amended to end with a period". However, this is not so.

Claim 66 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

- n) The applicants' stated that "aminoethyl in claim 42 is changed to amino-ethyl". However, it is the numeral indication of the point of attachment in the species which is questioned. The species on page 18, i.e. N-[1(R)-(3-Amino-ethylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-2-methyl-3-(4-oxo-3,4-dihydro-[1,5]-

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benzothiazepin-5-yl)propionamide indicates that the amino is attached to the third carbon atom, however, ethyl only has two carbon atoms.

Claim 67 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

In view of the amendment dated August 22, 2002, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 61-66 and 68-84 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

- a) The amendment to the definition of the substituents on the ring constituting A² where A² may be substituted by at least one group selected from acyl or acylamino is not described in the specification. (Claims 61-66 and 68-84)

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- b) The amendment to the definition of B where B is hydroxyarylalkyl or aryloxyarylalkyl is not described in the specification. (Claims 61-63, 65, 66, 68-81, 83 and 84)
- c) The amendment to the definition of R^2 and R^3 where R^2 and R^3 are independently hydroxy alkyl, arylalkyl which may be substituted on its aromatic ring or arylalkoxyalkyl which may be substituted on its aromatic ring is not described in the specification. (Claims 61-64 and 68-84)
- d) The amendment to the definition of the substituents on the ring A^4 where A^4 may be substituted by a group selected from acylamino is not described in the specification. (Claim 62)
- e) The amendment to the composition of claim 69 where the additional components are selected from a growth hormone is not described in the specification. (Claim 69)

Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 61-66 and 68-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

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- a) Claim 61-66 and 68-84 are vague and indefinite in that it is not known what is meant by "substituted" in the definition of R^2 and R^3 . "Substituted" without reciting intended substituents renders the claim unclear and indefinite as to number and nature of substitution.
- b) Claim 62 is vague and indefinite in that it is not known what is meant by the definition of R^4 where R^4 is $(C_1 \square C_5)$ alkyl or $(C_3 \square C_8)$ cycloalkyl.
- c) Claim 64 is vague and indefinite in that it is not known what is meant by "amino, phenyl" which appears twice in the definition of B.
- d) Claim 65 is vague and indefinite in that it is not known what is meant by " $(C_1 - C_5)$ alkyl" which appears twice in the definition of R^2 and R^3 .
- e) Claim 65 is vague and indefinite in that it is not known what is meant by " $(C_1 - C_5)$ alkyl" which appears twice in the definition of R^5 , R^6 , R^7 and R^8 .
- f) Claim 65 recites the limitation " R^5 can be taken together with R^1 and R^2 to form alkylene" in the definition of R^5 , R^6 , R^7 and R^8 . There is insufficient antecedent basis for this limitation in the claim.
- g) Claim 65 is vague and indefinite in that it is not known what is meant by the definition of R^9 and R^{10} which is not stated in the alternative.
- h) Claim 66 recites the limitation "2-hydroxymethyl" in the 6th moiety of the first column on page 10 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.

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- i) Claim 66 recites the limitation "2-aminomethyl" in the 7th moiety of the first column on page 10 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- j) Claim 66 recites the limitation "N-aminopropyl" in the 2nd moiety of the second column on page 10 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- k) Claim 66 recites the limitation "N-aminoethyl" in the 3rd moiety of the second column on page 10 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- l) Claim 66 recites the limitation "N-hydroxyethyl" in the 4th moiety of the second column on page 10 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- m) Claim 66 recites the limitation "N-hydroxyethyl" in the 5th moiety of the second column on page 10 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- n) Claim 66 recites the limitation "N-aminoethyl" in the 6th moiety of the second column on page 10 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.

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- o) Claim 78 recites the limitation "2-hydroxy" in the 1st moiety in the third row on page 21 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- p) Claim 78 recites the limitation "N-aminopropyl" in the 2nd moiety in the third row on page 21 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- q) Claim 83 recites the limitation "2-hydroxymethyl" in the 6th moiety of the first column on page 25 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- r) Claim 83 recites the limitation "2-aminomethyl" in the 7th moiety of the first column on page 25 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- s) Claim 83 recites the limitation "N-aminopropyl" in the 2nd moiety of the second column on page 25 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- t) Claim 83 recites the limitation "N-aminoethyl" in the 3rd moiety of the second column on page 25 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.

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- u) Claim 83 recites the limitation "N-hydroxyethyl" in the 4th moiety of the second column on page 25 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- v) Claim 83 recites the limitation "N-hydroxyethyl" in the 5th moiety of the second column on page 25 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- w) Claim 83 recites the limitation "N-aminoethyl" in the 6th moiety of the second column on page 25 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- x) Claim 84 recites the limitation "2-hydroxy" in the 1st moiety in the third row on page 27 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- y) Claim 84 recites the limitation "N-aminopropyl" in the 2nd moiety in the third row on page 27 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays and Tuesdays from 9:00 AM to 3:00 PM and from 5:30 PM to 7:30 PM and on Wednesday thru Friday from 9:00 AM to 6:00 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


Brenda Coleman
Primary Examiner AU 1624
October 25, 2002